

Maryland Board of Pharmacy
June 21, 2006

MINUTES

- I. Introduction/Recusals** - Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board. Mr. Donald Taylor recused himself from the discussion of the Practice Committee presentation involving *Electronic Alternative Process* since the request was submitted from a representative of his employer, Rite Aid.

Attendance

Officers: John Balch, President, Mark Levi, Treasurer, and Donald Taylor, Secretary

Commissioners: David Chason, Joseph DeMino, Jeanne Furman, Mayer Handelman, Rodney Taylor, Donald Yee and Margie Ann Bonnett

Absent Commissioner: Michael Souranis

Board Staff: LaVerne Naesea, Executive Director; Shirley Costley, Licensing Manager; Pat Gaither, Administration and Public Support Manager; Summar Goodman, PIO; Anna Jeffers, Legislative Officer; Colin Eversley, Compliance Investigator; and Briget Melvin, Recording Secretary

Board Counsel: Linda Bethman

Guests: Mike Swarner, Target; Catherine Putz, PEAC; Georgette Zoltani and Chandra Mouli, Division of Drug Control; Stephanie Nowak, HPS of Baltimore(LTC Pharmacy) Howard Schiff, Maryland Pharmacist's Association; and two students from the University of Maryland School of Pharmacy

II. Approval of Minutes May 17, 2006

Page 3, under VB.: 3rd line, add "type of" after "requested what"; 5th line, change "Zolantl, Deputy" to "Zoltani, Chief"; and 2nd paragraph, beginning at 1st line, delete "the increase in"

Page 4, under VI.: 2nd line, add "s" to "Pharmacist"

Page 5, under VIII, *Pseudoephedrine*, add word "Practice" before "committee"; and under 1st motion, add change "move" to "moved"

Page 7, under 1st motion, add period following "Medicaid requirements".; delete "and that there were no other recent changes to MD laws regarding pre-printed prescription pads"; and under b., 1st line, add "an automated medication system in a" before the word "hospice"

Page 8, under XA., 3rd paragraph, 1st line, following, “Matthew Smith” add “Data Support Assistant,”

Page 10, under XIII DTM Committee, 2nd line, delete “tobacco and dependence cessation and for metabolic syndrome” and add “Metabolic Syndrome and Tobacco Use and Dependence”

Motion: Joseph DeMino moved to accept the minutes with corrections.

Board Action: The Board accepted the motion.

III. President/Executive Committee Report – John Balch

A. New Assignments to Committees

President Balch noted that the new committee assignment document contained in the Board packets was a draft. He announced changes to that document as follows:

Disciplinary Committee - Mayer Handelman will continue to chair the committee, Rodney Taylor is newly assigned and Mark Levi's name should be removed as a member.

Licensing Committee - Michael Souranis is newly assigned as the chair and Rodney Taylor's name should be removed from the draft document. Jeanne Furman will continue on that committee.

Pharmacy Technician Sub-committee – The group was listed on the draft as a Task Force, but is an assigned Sub-committee of the Practice Committee. It will develop recommendations for the Pharmacy Technician regulations.

Wholesale Distributors Sub-committee – This is a newly appointed Sub-committee assigned to draft recommendations for amendments/revisions to the existing regulations before the next legislative session begins.

President Balch congratulated the Board staff on the recent move of the Board offices and announced that there would be a June 30th Pharmacy Technician photo opportunity with Governor Erhlich in Annapolis.

IV. Executive Director's Report – LaVerne Naesea

Ms. Naesea reported that the Board staff has completed the move from the third floor to the first floor of the Patterson Avenue building and that there may still be some temporary technical difficulties with the telephone system. An Open House is planned sometime between the Fall and December 2006.

Don Taylor reported that he attended the MPhA annual meeting and commended the organization for a well-executed meeting. Summar Goodman hosted a booth at the meeting for the Board.

V. PEAC (Pharmacist Education and Assistance Committee) Client Update

Catherine Putz reported for PEAC that Tony Tommasello made a presentation at the MPHA meeting. A PEAC monitor meeting is scheduled on June 25, 2006. Early intervention will be promoted to permit holders in order to increase awareness of the PEAC committee and its work. The committee is open to volunteers and the group is in the process of trying to enroll more impaired pharmacists into the program. According to Ms. Putz, there are many pharmacists who may need assistance through PEAC. Ms. Putz noted that Mr. Tommasello provided the program statistics to the Disciplinary Committee at its last meeting.

Mr. Mouli of the Division of Drug Control (DDC) reported that its report of pharmacy inspections performed would be provided for inclusion in the next Disciplinary Committee meeting packet. Ms. Zoltani, of DDC, stated that the Division of Drug Control presently has four pharmacist inspectors and two pharmacist inspector vacancies.

VI. Legislation and Regulation Manager Report – Anna Jeffers

A. Legislation - The Pharmacy Technician Bill Photo Op in Annapolis is scheduled for June 30, 2006.

B. Regulations – A Pharmacy Technicians Sub-committee has been assigned to recommend regulations. Three meetings are set for the Summer with plans to review and amend the draft prepared earlier for the 2005 failed pharmacy technician legislation. An informal copy of the draft regulation will be sent to stakeholders for comment before being formally proposed in the Maryland Register.

The Board considered and approved the recommended *Prescription Drug Repository Program regulations* as amended. The revised draft will be submitted to the Executive Committee for final approval before submission as formally proposed regulations. Specific amendments included:

Under .04, B, delete (5); Under .05A, delete (3); Under .05D(5), change *a secure box* to *an area that limits access to the prescription drug to those pharmacists or health care practitioners who have been assigned the responsibility to accept the donated prescription drugs or medical supplies*; Under .06A, delete (3); Under .06D(1) at the end of the line, change *and* to *or*.

Motion: Mark Levi moved to accept the Prescription Drug Repository Program Regulations as amended.

Board Action: The Board approved the motion.

The Board accepted the proposed amendment to the Pharmacist Administration of Influenza Vaccination regulation that would allow a fee to be charged for the cost of the vaccine, but limit the fee to not exceeding Medicare reimbursement rates. The proposal will be submitted to the Board of Physicians and the Board of Nursing for final review before submitting the proposed amendment to the Maryland Register for public comment.

Motion: Donald Taylor moved to accept the proposed action as submitted.

Board Action: The Board approved the motion.

Regarding the Licensing of Wholesale Prescription Drug or Device Distributors sub-committee, Delegate Stern received the Board's invitation to assign a staff member to the sub-committee. She responded that she may send a representative to some of the meetings and requested notices of meetings and copies of the meeting minutes.

VII. Administration and Public Support – Patricia Gaither

Personnel Update

Ms. Gaither reported that the Board anticipates the Pharmacist Compliance Officer position to be filled before the end of July 2006. She stated that the proposed candidate is both a pharmacist and an attorney. The Board is revising the requirements for the Compliance Specialist position to include mental health experience because the Board may be revising its program for monitoring impaired pharmacists. The Legislative/Regulations Manager's position is being reclassified, and a program officer will be recruited to join the Legislative/Regulations Unit once the reclassification process is completed.

Three other positions that are in the process of recruitment include: Administrative Specialist II and Secretary I for the Pharmacy Technician Program to be housed in the Licensing Unit; and the Secretary III position to serve as secretary and board receptionist.

Third Quarter Budget Report

Ms. Gaither directed members to the report included in the Board packet (Board members only). She stated that the salaries and special contracts (PEAC, Towson MIS and Drug Therapy Management) were included. She stated that overall the Board remains within the projected budget for FY 2006, even though in some categories the Board anticipates overspending due to the office move. She also mentioned that the FY 2007 budget has been approved at \$1.9 million.

All Board member expense reports must be submitted to Ms. Gaither before July 1, 2006.

Public Information Officer Report – Summar Goodman

Ms. Goodman circulated copies of the Spring newsletter at the meeting and reported that it has been mailed. She noted that although there were delays in printing due to the contract ending with an outside vendor, the newsletter was still mailed before the start of Summer. Board members and unit managers were provided with the schedule for the next issue and asked to adhere to the submission deadlines listed. It was agreed that future articles would mention not only the Board/staff authors' names, but also their positions/titles with the Board (e.g., committee chair, unit manager, etc.). Ms. Goodman asked members and the public to continue submitting ideas for articles in future issues. Ms. Furman reminded members that a patient safety article should be included in every issue of the newsletter.

NABP District I & II Meeting Update

The draft sponsor packet was included in the board packet, which indicated sponsorship levels and marketing opportunities. Concerns were expressed regarding fundraising efforts and securing speakers. Board members asked that fundraising efforts and amounts secured be reported at all future meetings. Ms. Goodman noted that all referrals and potential sponsor contacts have been sent to the School of Pharmacy. The School is responsible for fundraising and scheduling speakers for the continuing education sessions. The Board is responsible for the hotel arrangements, securing special guests, planning meals, and other entertainment venues. However, decisions regarding many of these arrangements are dependent on the levels of funds and sponsorships secured by the School. It was noted that the School's consultant's, Anna Leonhart, contract does not include fundraising.

Ms. Furman noted that the Board should have pre-approved the change to CE content. Specifically, another speaker has been added to discuss counterfeit drugs. She stated that this addition may be excessive since author Katherine Eban will be addressing the subject and most of the attendees have been extensively exposed to the subject matter at other NABP meetings.

VIII. Management Information Services – Tamarra Banks

MIS Status Report

Ms. Banks reported that the installation of the in-house database under contract with Towson University is on-going. In addition to recruitment of a Database specialist to fill the MIS Unit vacancy, a contractual Help Desk employee will still be required to manage the web site and perform day-to-day troubleshooting for staff and Board member computer problems.

Additional laptop computers need to be purchased for new Board employees.

IX. Committee Reports

A. Emergency Preparedness – Donald Taylor

Ms. Naesea reported that Deputy Secretary Michele Gourdine has requested that the Board's list of volunteers go to all the local health departments. The Emergency Preparedness Committee has traditionally retained control of the volunteer list so as to avoid conflicts with local health departments when there is a need to deploy volunteers in actual emergencies. Mr. Don Taylor asked the Board to vote to decline responsibility for recruiting and training volunteers if it would not have the authority to exclusively retain its volunteer list. He also mentioned that the State offers liability protection that local health departments may not offer (depending on the jurisdiction).

Motion: Jeanne Furman moved that the Board request to not release the volunteer list to local health departments and to request that the Board be relieved from responsibility for recruitment and training of volunteers if the request is denied.

Board Action: The Board approved the motion.

The Emergency Preparedness on-line CE training mail merge letters are in draft format and will be mailed once approval is received.

Mr. Taylor also mentioned that the Board and Committee are working on a system for renewing the volunteer identification cards that will expire in October 2006.

B. Practice Committee – Mark Levi

Constituent Responses Letters

Automatic Pharmacy Admixture System

Mr. Syed Hussain asked the Board about state requirements for installing an automatic pharmacy admixture system in a hospital pharmacy. Mr. Chason briefly described to the Board how automatic admixture systems usually operate and noted that as long as the patients are on the same hospital campus, the drugs do not have to be patient specific. If done off the hospital campus, it would be manufacturing and not allowed by Maryland law.

Motion: Jeanne Furman moved to accept the proposed response letter that stated that compliance with state COMAR 10.34.19 Parenteral/Sterile Enteral Compounding and with USP <797> is required.

Board Action: The Board approved the motion.

Electronic Alternative Process

Mr. Michael A. Podgurski, of Rite Aid, asked the Board if the pharmacies' daily reports could be kept electronically. The Board approved doing so as long as the reports are *readily* retrievable.

Motion: Rodney Taylor moved to accept the proposed letter with the change of the word 'easily' to the word 'readily'.

Board Action: The Board accepted the motion with the change of the word 'easily' to the word 'readily'.

Respiratory/Oxygen

Ms. L. Frost, a durable medical equipment provider, asked what regulations would apply for keeping saline in her center. The proposed response referred the inquirer to the Office of Health Care Quality, which is responsible for regulating residential services agencies. Members added that as long as the drug is not a legend drug it may be kept on the premises.

Motion: Mayer Handelman moved to accept the proposed letter with the amended language.

Board Action: The Board approved the motion.

Methadone Clinics

Pam Collins asked the Board about dispensing take home methadone to patients. Nurses do not normally dispense. The letter provokes the question whether the law should be changed to accommodate this. Linda Bethman reported that many methadone clinics are automated at this point. Presently, nurses are dispensing. Linda Bethman spoke with the counsel for ADAA and MHA who stated that Peter Luoango, Director for MHA, is exploring ways to address this issue. Mr. Luoango will be invited to meet with Ms. Naesea, Mr. Balch, Mr. Levi and Ms. Bethman to discuss the issue.

Long Term Care Task Force – John Balch

The LTC committee will create a list of bulk medications that would be acceptable in LTC facilities. This list will be given to Office of Health Care Quality (OHCQ) for them to maintain. The list will be finalized at the August LTC meeting. MD is one of only four states that do not allow bulk medicines to be dispensed in LTC facilities.

C. Licensing Committee – Joe DeMino

Committee Updates

The Licensing Committee met on June 19, 2006. New certificates for administration of the influenza vaccine will be mailed to approved candidates. The Board has certified five pharmacists since promulgation of the influenza regulations.

The Board will begin accepting pharmacy technician registrations in January 2007. The Committee will work on program implementation throughout the summer. It is considering allowing on-line registration from the start of the program. Registrations will likely expire every two years at the end of the technicians' birth month (as with the pharmacist licensing program).

Howard Schiff (MPhA) mentioned concerns regarding the Board's new system of mailing post cards to encourage on-line renewals. He stated that currently, most pharmacists do not renew on-line. Mr. Schiff was informed that in keeping with new technology trends, most State Boards use similar systems and that the new system is intended to encourage pharmacists to begin renewing on-line. The Board will still

provide renewing pharmacists the option of submitting hardcopy renewal applications if that is their preference.

May Statistics - Statistics were included in the June Board packets.

Constituent Responses Letters

Foreign Graduate Internship Hours

In response to a foreign graduate pharmacist applicant's request to accept internship hours from New York, the committee informed him that in accordance with the Board's new policy, hours would not be accepted unless the applicant formally registered and the internship program was approved by the New York Board of Pharmacy.

FDA Internship Hours

The Board accepted the Licensing Committee's recommendation that it allow internship hours from FDA to be applied towards required internship hours. However, hours may not be applied if they were earned as part of the PEP program at the applicant's school.

Influenza Vaccine Regulations

An Anne Arundel County constituent questioned whether the influenza regulations would be applicable to vaccines against the avian flu. Broadly speaking the response is yes, however, the matter was referred to the Practice Committee for further consideration.

Reciprocity from Another State

The committee responded to a New York reciprocity candidate that he would not be required to take the FPGE in Maryland to become licensed since he was already licensed in Tennessee and has passed the NAPLEX examination.

D. Disciplinary Committee – Mayer Handelman

Mr. Handelman began by welcoming Board member Rodney Taylor to the Disciplinary Committee. Mr. Handelman stated Committee concerns regarding medication errors for the more dangerous drugs that are dispensed to patients (e.g., Coumadin). He questioned what policies and procedures currently exist for high-risk medications and stated that the Committee would like to see specific guidelines issued, perhaps by permit holders. Mr. DeMino stated that his company has already issued policies and procedures (INSP List).

Mr. Handelman further suggested that the Disciplinary Committee initiate a study to determine from which colleges pharmacists, who commit medication errors, graduate. Following some discussion, it was determined that the study would not be performed.

Representatives of the Division of Drug Control (DDC) asked about the status of the revised Inspection Reports. Mr. Souranis is still processing the document and will arrange for training DDC inspectors in the near future.

X. Informational Materials

- A. Letter and Fact Sheet from Center for Substance Abuse Treatment
Heroin Fentanyl
- B. Ben Steffen – Practitioner Utilization
- C. FDA Requests Comments on Proposed Rules for Medical Gas
Containers and Closures
- D. Institute for International Research - Symposium
- E. DEA – Public Meeting to Discuss Electronic Prescriptions for
Controlled Substances
- F. National Provider Identifier